SEP 1 1 2000

Asclepion

K002032

Asclepion-Meditec AG Pruessingstrasse 41, 07745 Jena, Germany

510(k) SUMMARY

CO2 Laser Multipulse

This 510(k) summary of safety and effectiveness for the Asclepion-Meditec AG CO2 Laser Multipulse is submitted in accordance with the requirements of 21 CFR Part 807 Subpart E § 807.92 and follows the DSMA Office of Health and Industry Programs Guidance: Premarket Notification 510(k) – Regulatory Requirements for Medical Devices (HHS Publication FDA 95-4158, August 1995) concerning the requirements for a 510(k) Summary and Statement.

Applicant:	Asclepion-Meditec AG
Address:	Pruessingstrasse 41 07745 Jena, Germany
Contact Person:	Dr. Dirk Colditz Quality Management Representative
Phone: **Fax:** **e-mail:**	+49 3641 65 3453 +49 3641 65 3448 ctz@asclepion.com
Preparation date:	June 22nd, 2000
Device name:	CO2 Laser Multipulse
Common Name:	Multipulse
Classification Name:	General and Plastic Surgery – Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810) Product code: GEX – Laser Instrument, surgical, powered Panel: SU
Legally marketed devices (SE):	AESCULAP-MEDITEC GMBH Multipulse 30 (K983215), M.L.T Ltd. MLT 30 (K982548), Coherent Ultrapulse 2500C (K963339) Sharplan 30C(K963229), Tissue Technologies TruPulse (K970804)
Device Description:	The Asclepion-Meditec CO2 Laser Multipulse emits a beam of coherent light at the wavelength 10.6 microns with a maximum power of 30 Watt.
Intended Use:	The Asclepion-Meditec AG CO2 Laser Multipulse is intended for the coagulation, ablation, vaporization, incision, excision, or cutting of soft tissue in plastic surgery, general surgery, oral surgery, E.N.T, gynecology, and dermatology. The Multipulse is restricted to sale to or use by licensed professionals in the United States.

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Comparison to: The specifications of and indications for the Asclepion-Meditec AG CO2 Laser Multipulse are the same as or very similar to those of the claimed predicate devices AESCULAP-MEDITEC Multipulse 30 (K983215), M.L.T. Ltd. MLT30 (K982548), Coherent Ultrapulse 2500C (K963339), Sharplan 30C (K963229), and Tissue Technologies Tru-Pulse (K970804).

Performance data: None. The specifications and intended uses of the Multipulse are the same or very similar to those of claimed predicate devices. Because of this , performance data were not required.

CONCLUSION: Based on the similarities of specifications and indications for use, Asclepion-Meditec AG believes that the CO2 Laser Multipulse described in this notification is substantially equivalent to the cited legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2000

Asclepion-Meditec AG
c/o Dr. Dirk Colditz
Quality Management Representative
Asclepion-Meditec, Inc.
2525 McGaw Avenue
Irvine, California 92623

Re: K002032
Trade Name: CO2 Laser Multipulse
Regulatory Class: II
Product Code: GEX
Dated: June 22, 2000
Received: July 3, 2000

Dear Dr. Colditz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002032

Device Name: CO2 Laser Multipulse

Indications For Use:

The Asclepion-Meditec AG CO2 Laser Multipulse is intended for the coagulation, ablation, vaporization, incision, excision, or cutting of soft tissue in plastic surgery, general surgery, oral surgery, E.N.T, gynecology, and dermatology.

The Multipulse is restricted to sale to or use by licensed professionals in the United States

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002032

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)